

Vulnerabilities and opportunities in scientific research

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Valorisation

By exploring the experiences and perspectives of people from sub-Saharan African countries involved with clinical trials, as well as the context in which these activities take place, my dissertation provides analysis and insight into the ways certain people engage and construct meaning around clinical trials and participation. To provide this knowledge I studied interventional clinical trials and the local participation of citizens in trial settings from Ghana and across Tanzania. As demonstrated in the previous chapters of this of this book, I used this information to highlight the potential impact perceptions and approaches to participation can have in developing more sustainable and mutually beneficial research frameworks, policies and practices. Thus, this can help further contribute to creating a bridge between the different perspectives and approaches that have resulted in tensions arising between global clinical trial processes and the local involvement of trial participants.

Value for innovation in clinical trials

Dynamic engagement - the involved participant

The work done in this thesis mainly focuses on participant voices from lower resourced settings and their perceptions of clinical trial involvement. The people involved in my research span from highly educated university students to farmers having little to no formal education, all providing important ideas about what it means for them to be involved in trials and what trials come to represent for them. Thus the findings arising from these insights makes the work that I present in this thesis valuable for providing a broader understanding of local concerns, expectations, and tensions embedded in alternative points of view, for research ethics committees who are tasked with determining the scientific merit of research and ensuring that the rights of research participants are observed and respected. As my work demonstrates, the perspectives held by participants about trials and the processes that guide them are not always in line with those actors charged with conducting and overseeing research. Often it seemed as though the answer to dealing with these alternative perspectives was to provide more knowledge and education to participants to converge any potentially misaligned ideas. However, such an approach reinforces the idea of hierarchy and dismisses the relevance of local voices. Instead, my work supports the need for continuous engagement with local voices, and for all stakeholders – with the inclusion of trial participants – to work together over the course of the trial to develop practices and frameworks that in turn would be of greater overall benefit to those supporting research through participation in lower resourced settings; whether through improved information sharing, resource distribution, or the general improvement of clinical trial quality and the development of useful interventions needed in the local communities.

Additionally, the work that I have conducted in this thesis highlights the need for clinical trials to take on a more reflexive and inclusive approach to trial participation, particularly in settings where trial research conduct has not been well-established yet. While it is not uncommon for there to be separation between members of research ethics committees, researchers and participants, the work that I have done points to a desire for more dynamic engagement in research. Rather than being passive trial participants, what is seen is a desire to be made a part of what is happening with trials and trial outcomes, whether this is debriefing and the conclusion of a trials, or the ability of participants, researches, and ethical committee members to engage and discuss during the course of the trial. In my analysis I have shown

that this is informally already taking place during scheduled appointments, in the trial waiting rooms, or during unscheduled visits to the research centres by participants who feel fully invested in the outcome of research. My work shows the potential benefit of providing a more formal mechanism through which this process can happen; leading to tensions being worked out before they become irreversibly problematic, misaligned perspectives on issues such as what constitutes risks and benefits becoming an ongoing discussion rather than fixed concepts, and relatedly, the job of ethics committee members being seen as continuous throughout the course of the trial, instead of essentially concluding before the actual commencement of the trial.

Context as an active element of participation

Furthermore, there is great value provided by this research, in that it looks at participation, decision-making and trial conduct in relation to context. The framework which governs international clinical trials, including the following of international guidelines like CIOMS, and the Helsinki declaration underscores a connection between the context in which trials take place and the safety, benefit and welfare of participants in trials. The added value my work brings is that it provides deeper insight into how exactly context plays a role in developing understandings, perspectives and decision-making by participants who are involved with trials in lower resourced settings. This information is valuable for both sponsors of research who intend to do work in such settings and research ethics committee members, and institutional review boards who are trying to assess the impact of trials on participants and the local community. This research provides more information as to how context may or may not influence vulnerability of potential research participants, how context is involved in the development of perspectives in lower resourced settings, and the impact this has on participant decision-making. The focus of this research centred on lower resourced trial participation in sub-Saharan Africa. However, the lessons provided by it also serve as reflection points from which participation of individuals from lower resourced communities across the globe, including in higher income countries, may also be explored and strategies for improved trial involvement developed.

Valorisation in Practice

One way in which this research attains value is through its dissemination in the form of published scholarship, to those who would benefit from its results. This includes not only researchers, sponsors, academics, and members of institutional review boards and research ethics committees, but participants themselves, who have explicitly requested to receive the findings of the work I conducted. As such, the empirical chapters of this book have been either published or prepared for publication in academic journals (see publication list for overview of texts).

However, publications are only one way in which research results and insights can be shared. Over the course of my research I have also used conferences and workshops as a platform in which to share my findings and actively engage in discussion about the impact and potential value of my work. I have presented and discussed my work in several relevant events:

Relevant conferences:

- FOREIGN BODIES IN CONVERSATION: a public symposium for those researching global health. The Jan Van Eyck Academie (2017), I organized this conference to bring together actors in health that normally would not get to come together in such an environment to discuss clinical trials from various discipline perspectives

- Revealing discourses: (re)imagining innovation and governance through international clinical trials, EASST/4S Conference Science & technology by other means: Exploring collectives, spaces and futures, Barcelona, Spain (2016)
- “Dreaming of Health and Science in Africa: Aesthetics, Affects, Poetics and Politics” conference (2015) <https://africanbiosciences.wordpress.com/events/dreamingscience>
- “Oxford Global Health Bioethics International Conference” (2015) <http://www.ndph.ox.ac.uk/upcoming-events/global-health-ethics>
- “International conference Social Sciences and Medical Innovations” (2014), where I spoke about and shared my findings on the meaning giving to trial participation by Ghanaian citizens

Relevant workshops/meetings:

- workshop on Ethical Review in Global Health (2018) hosted by Amsterdam public health consortium
- NIMR Mwanza Research Centre (MRC) clinical trials meeting (2015), where I participated and engaged with government officials, international trial sponsors, research staff and industry representatives sharing the results of my findings
- (Invited talk) International biomedical research: science, society, and pharmaceutical innovation & development, Center for Bioethics and Social Sciences in Medicine seminar, Michigan, USA (2015), spoke to various medical, health and educational staff with a vested interest in clinical trials and participation about my work